

The safety and utility of a novel automated mechanical endoscopic tissue resection tool for endoscopic necrosectomy

Submission date 27/09/2018	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 16/10/2018	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 18/01/2021	Condition category Digestive System	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Acute pancreatitis is a sudden inflammation of the pancreas. The most common cause of acute pancreatitis is gallstones, other known causes include amongst others alcohol use, trauma, medication and high lipid (fat) levels. In 80% of patients pancreatitis is mild and settles within a week or two. In about 20% of patients the pancreatitis becomes severe. Parts of the pancreas may die (necrose). When the necrosis becomes infected, treatment is virtually always necessary. Infected necrosis is associated with a mortality (death rate) of 20% and many other complications. A lot of studies have been performed to optimize the treatment strategies for these patients. Endoscopic drainage of the abscess and necrosectomy (actively remove the necrotic tissue) have been shown to be effective. However, currently no effective tool is available to remove the necrotic tissue. The aim of this study is to evaluate a novel tool (the EndoRotor) to endoscopically remove necrotic tissue.

Who can participate?

Patients aged 18 and over with acute necrotizing pancreatitis

What does the study involve?

Patients undergo endoscopic drainage and necrosectomy. The only difference is that the necrosectomy is performed using the EndoRotor. Technical success is defined as complete removal of the pancreatic necrosis at the discretion of the treating physician.

What are the possible benefits and risks of participating?

There are no additional risks with participating in this study besides known risks for necrosectomy. Possible benefits include fewer procedures to achieve complete removal of pancreatic necrosis and shortened length of hospital stay.

Where is the study run from?

Erasmus University Medical Center (the Netherlands) and Sana Klinikum Offenbach (Germany)

When is the study starting and how long is it expected to run for?
October 2016 to December 2018

Who is funding the study?
Erasmus University Medical Center (Netherlands)

Who is the main contact?
Dr A.D. Koch

Contact information

Type(s)
Scientific

Contact name
Dr A.D. Koch

Contact details
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3015 GD

Additional identifiers

Protocol serial number
MEC-2018-1426

Study information

Scientific Title
Safety and efficacy of the EndoRotor® for endoscopic treatment of patients with acute necrotizing pancreatitis

Acronym
EETAP

Study objectives
The EndoRotor is an effective endoscopic tool for the removal of pancreatic necrosis in patients with acute necrotizing pancreatitis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Erasmus University Medical Center Ethics Committee, 17/09/2018, ref: MEC-2018-1426

Primary study design

Observational

Study design

Prospective multicenter study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Acute necrotizing pancreatitis

Interventions

Patients (male and female, aged over 18 years) were treated for (infected) necrotizing pancreatitis. Patients underwent transluminal drainage followed by direct endoscopic necrosectomy using the EndoRotor. Details on the procedure with the EndoRotor were identified; duration of the procedure, number of interventions to completely remove necrotic tissue, and procedural complications. Patients were followed during their hospitalization.

Intervention Type

Device

Primary outcome(s)

Technical success: this was defined as complete removal of the pancreatic necrosis at the discretion of the treating physician. This was disregarding the number of necessary interventions.

Key secondary outcome(s)

1. The incidence of complications associated with the endoscopic treatment, evaluated during the procedure and after the procedure during admission
2. Total number of interventions to achieve complete removal of pancreatic necrosis

Completion date

01/12/2018

Eligibility**Key inclusion criteria**

1. Male and female
2. Aged 18 years or older
3. Acute necrotizing pancreatitis

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

Inability to undergo endoscopic treatment due to comorbidity

Date of first enrolment

01/01/2017

Date of final enrolment

27/07/2018

Locations**Countries of recruitment**

Germany

Netherlands

Study participating centre

Erasmus University Medical Center

Dr. Molewaterplein 40

Rotterdam

Netherlands

3015 GD

Sponsor information**Organisation**

Erasmus University Medical Center

ROR

<https://ror.org/018906e22>

Funder(s)**Funder type**

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr A.D. Koch (a.d.koch@erasmusmc.nl)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	preliminary results	21/02/2020	13/07/2020	Yes	No